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| EXAMINER | |
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| ALLISON, ANDRAE S | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/717,861 | TUREK ET AL. | |
| | Examiner | Art Unit | |
| | Andrae S. Allison | 2624 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *Amendment filed on May 21, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Remarks*

1. The Office Action has been issued in response to amendment filed May 21, 2007. Claims 1-75 are pending. Applicant's arguments have been carefully and respectfully considered in light of the instant amendment, and are not persuasive. Accordingly, this action has been made FINAL.

*Response to 102 Rejection Arguments*

In response to applicant's argument on page 16, [p][002] that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. analysis software executable on a personal computer of a patient and downloading medical images of the patient produced by the imaging apparatus to the personal computer of the patient) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues on page 16, [p][002] that Iliff does not teach an analysis software executable on a personal computer of a patient and that the disease management software cannot be reasonably interpreted as the analysis software, however, the Examiner disagrees with both positions. Iliff clearly teaches that a script accessing a patient condition can be run from a server or the script can reside on the

user computer (see column 6, lines 59-67), which is the patient's computer (116, see Fig 1). Also the disease management software can be reasonably interpreted as the analysis software since the disease management software does analysis automatically base several factors such as reviewing and adjusting therapy levels based on dialog with the patient (see column 12, lines 49-67).

*Response to 103 Rejection Arguments*

In response to Applicant's argument on page 18, [p][0001-004], that Chalana fail to disclose the limitation analysis software executable on a personal computer of a patient, however, Chalana was not relied up for the above limitation. Furthermore, note that the limitation was not recited in the rejected claims.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 40-44, 52, 54, 57-61, 74-77, 79, 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (US Patent No.: 6,901,277) in view of Iliff (US Patent No.: 6,234,964) .

As to independent claim 57, Kaufman discloses a method for at least one of detecting, quantifying, staging, reporting, or tracking of a disease (generate organ report

to track and analyze lung nodules; column 1, lines 18-21), said method comprising: imaging a patient (acquire images of patient's lung; column 8, line 43 ) with a medical imaging apparatus (12, imaging device; see Fig 4); downloading medical images of the patient produced by the imaging apparatus to a personal computer of the patient (column 11, lines 25-37 ); and repeating said imaging and downloading a plurality of times at intervals selected to provide said analysis software with sufficient images to at least one of detect, quantify, stage, report, or track the disease in the patient (see column 11, lines 9-23 and lines 25-37, where a first and a second follow scan is done of the patient's lung and downloaded to a computer) by computer analysis of the images via the analysis software executable on the personal computer of the patient.

However, Kaufman does not expressly disclose the computer analysis of the images via the analysis software executable on the personal computer of the patient and downloading medical images of the patient produced by the imaging apparatus to the personal computer of the patient. Iliff discloses disease management method (column 1, lines 12-14) that includes said analysis software executable on a personal computer of a patient (note that a disease management module can be executed on patient computer, see column 6, lines 59-67 and column 13, lines 12-27) and downloading medical images of the patient produced by the imaging apparatus to the personal computer of the patient (see column 8, lines 23-26, where a patient can access a database of different image modalities).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the teaching of Kaufman with the teachings of Iliff to

provide a computerized disease management method for assessing the health condition of a patient having a disease e.g. chronic obstructive pulmonary disease, and optimize disease therapy based on the health assessment (column 2, lines 44-48 and column 21, lines 39-42).

As to independent claim 54, all the limitations are discussed above except: "a method for tracking a changeable parameter". Kaufman discloses a method for tracking a changeable parameter (generate organ report to track and analyze lung nodules; column 1, lines 18-21) of a person (a patient; column 4, line 43).

As to independent claim 40, all the limitations are discussed above except: "transmit results of said analysis to a remote database". Kaufman teaches transmitting results of said analysis to a remote database (see column 17, lines 39-42, where the operator's findings are stored in remote database 14).

As to claim independent 76, this claim differs from claim 57 only in that claim 79 is network whereas, claim 57 is method and the limitation an interface for transferring scanned images of a patient to a personal computer of the imaged patient is additively recited.

Kaufman clearly teaches a network (20, see Fig 3): an interface (30, see Fig 3) for transferring scanned images of a patient to a personal computer of the imaged patient (column 7, lines 30-34).

As to claim 58, Kaufmann teaches a method wherein said computer on a network (20, see Fig 3) is a computer at a workplace (column 7, line 22-23).

As to claim 59, Kaufmann teaches a method wherein said imaging apparatus is a computed tomographic imaging apparatus (column 8, line 43).

As to claim 60, Kaufman teaches a method wherein said imaging apparatus is a magnetic resonance imaging apparatus (column 8, line 43).

As to claim 61, Kaufman teaches method wherein said imaging apparatus is an x-ray imaging apparatus (column 8, line 48).

As to claim 74, Kauffman teaches a method wherein said analysis software is configured to analyze airway segmentation and perform multiple hypothesis tracking (tracing each nodules through a series of slice image; column 9, lines 46-54).

As to claim 75, Kaufman teaches a method, wherein said analysis software is configured to analyze a bronchial tree and to use multiple hypothesis tracking to piece a bronchial tree together from cross-sectional images (see column 9, lines 55-58 where a potential nodules is mapped out in each slice of image).

As to claims 41-44, note the discussion of claim 58-61 above. Claims 40-44 differ from claims 58-61 only in that claims 58-61 are method claims whereas, claims 41-44 are apparatus claims. Thus, claims 41-44 are analyzed as previously discussed with respect to claims 58-61 above.

As to claims 52, note the discussion of claim 75 above. Claim 52 differ from claims 75 only in that claim 75 is method claim whereas, claim 52 is apparatus claim. Thus, claim 75 is analyzed as previously discussed with respect to claim 52 above.

As to claim 77, Kauffman teaches a network further comprising a remote database (14, see Fig 7), and wherein said analysis software is configured to instruct a computer to transmit information relating to status of a patient's disease to said remote database (column 13, lines 35-45).

As to claims 79 and 81-83, note the discussion of claims 58-61 above. Claims 79 and 81-83 differ from claim 58-71 only in that claims 58-71 are method claims whereas, claims 79 and 81-83 are network claims. Thus, claims 79 and 81-83 are analyzed as previously discussed with respect to claims 58-61 above.

4. Claims 45-47, 49-51, 62-64, 69-73, 84-86 and 91-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (US Patent No.: 6,901,277) in

view of Iliff (US Patent No.: 6,234,964) further in view of Kotmel et al (Pub No.: US 2003/0055331).

As to claim 62, Kaufman discloses a method wherein said analysis software is configured to analyze tubular structures depicted in the medical images (e.g. colon, see column 6, line 47); however does not expressly disclose wherein the disease is chronic obstructive pulmonary disease.

Kotmel disclose a method for performing diagnosis testing on a lung ([p][005], lines 3-6) that includes where the disease is chronic obstructive pulmonary disease ([p][0006], line1). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have combined the teachings of Kauffman as modified by Iliff and Kotmel for acquiring and analyzing lung images to generate diagnosis information reflecting an individual lung compartment to quantify a disease state and for determining the most appropriate treatment plan ([p][0017], lines 1-10).

As to claim 63, note the discussion above, Kotmel teaches a method wherein the disease is selected from the group consisting of chronic bronchitis and asthma ([p][0006], line 4).

As to claim 64, note the discussion above, Kaufman teaches the method a method wherein said analysis software is configured to analyze bronchial wall cross-sectional area in the medical images ([p][0006], lines 19-21).

As to claim 69, note the discussion above, Kotmel teaches a method wherein the disease is chronic obstructive pulmonary disease ([p][0006], line1), and said analysis software is configured to analyze areas of a lung infected (e.g. emphysema, column 2, line 1) with the disease in the medical images.

As to claim 70, note the discussion above, Kotmel teaches a method wherein the disease is emphysema (column 2, line 1).

As to claim 71, Kaufman teaches a method wherein said analysis software is configured to divide an image of a lung into a series of regions to be analyzed (column 9, lines 9-13).

As to claim 72, note the discussion above, Kotmel teaches a method wherein the disease is chronic obstructive pulmonary disease ([p][0006], line1), and said analysis software is configured to analyze properties (e.g. density measurements, [p][0016], lines 11-13) of regions of a lung in the medical images.

As to claim 73, note the discussion above, Kotmel teaches a method wherein the disease is chronic obstructive pulmonary disease ([p][0006], line1) and said analysis software is configured to analyze region edges (see [p][0018], lines 6-10, where a software algorithm is used to determine the periphery of a lung compartment) lung in the medical images.

As to claim 50, note the discussion above, Kotmel teaches a portable computing device wherein the disease is chronic obstructive pulmonary disease ([p][0006], line1), and said portable computing device is configured to analyze intensity of regions (e.g. analyze periphery or edges regions, [p][0035], lines 1-3) of a lung in the medical images.

As to claims 45-47, note the discussion of claims 62-64 above. Claims 45-47 differ from claim 62-64 only in that claims 62-64 are method claims whereas, claims 45-47 are apparatus claims. Thus, claims 45-47 are analyzed as previously discussed with respect to claims 62-64 above.

As to claims 49 and 51, note the discussion of claims 69 and 73 above. Claims 49 and 51 differ from claim 69 and 73 only in that claims 69 and 73 are method claims whereas, claims 49 and 51 are apparatus claims. Thus, claims 49 and 51 are analyzed as previously discussed with respect to claims 69 and 73 above.

As to claims 84-86, note the discussion of claim 62-64 above. Claims 84-86 differ from claim 62-64 only in that claims 62-64 are method claims whereas, claims 54-86 are network claims. Thus, claims 84-86 are analyzed as previously discussed with respect to claims 62-64 above.

As to claims 91-97, note the discussion of claim 69-75 above. Claims 91-97 differ from claim 69-75 only in that claims 69-75 are method claims whereas, claims 91-97 are network claims. Thus, claims 91-97 are analyzed as previously discussed with respect to claims 69-75 above.

5. Claims 65-68 and 87-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (US Patent No.: 6,901,277) in view Iliff (US Patent No.: 6,234,964) further in view of Kotmel et al (Pub No.: US 2003/0055331) further in view of Vining (US Patent No.: 6,083,162).

As to claim 65, Neither Kaufman or Kotmel teaches a method wherein said analysis software is configured to utilize segmentation to isolate a selected tubular structure of interest in the medical images. Vining discloses a method for producing two-dimensional images (column 2, lines 23-24) that includes wherein said analysis software is configured to utilize segmentation to isolate a selected tubular structure of interest in the medical images (column 3, lines 1-4). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have added the method for producing two-dimensional images of Vining to the method of generating a lung report of Kaufman as modified by Iliff and Kotmel to acquire images, such as CT scans, to examine the tracheobronchronchial airway for disease, such as cancerous masses (column 1, lines 17-20 and column 2, lines 2-8).

As to claim 66, note the discussion above, Vining teaches a method, wherein

said analysis software is configured to measure bronchial wall cross-sectional area utilizing said isolated selected tubular structure of interest (column 7, lines 1-14).

As to claim 67, note the discussion above, Vining teaches a method wherein said analysis software is further configured to identify a center of an airway lumen (see Fig 23) in the medical images.

As to claim 68, note the discussion above, Vining teaches a method wherein said analysis software is configured to measure bronchial wall cross-sectional area utilizing said identified center of an airway lumen in the medical images (column 7, lines 1-14).

As to claims 87-90, note the discussion of claim 65-68 above. Claims 87-90 differ from claim 65-68 only in that claims 65-68 are method claims whereas, claims 87-90 are network claims. Thus, claims 87-90 are analyzed as previously discussed with respect to claims 65-68 above.

6. Claims 55-56, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (US Patent No.: 6,901,277).

As to claim 55, Kauffman does not expressly disclose a method to carried out on a plurality of persons or objects, utilizing a separate personal computer for each person or object. However, it would have been obvious to have the method carried out on a plurality of persons or objects, utilizing a separate personal computer for each person or

object so that each person participating in a clinical trial can access his/her medical information to track the progress of a treatment for a disease from his/her home or office (OFFICIAL NOTICE).

As to claim 56, Kauffman teaches a method further comprising aggregating said changeable physical parameters in a remote database (column 13, lines 67-68 and column 13, lines 1-4).

As to claim 79, Kauffman does not expressly disclose a network wherein said database is maintained by a pharmaceutical company. However, it would have been obvious to have a pharmaceutical company maintain the database so that scientist at the pharmaceutical company can track the effect of medicine during a clinical trial to access the effectiveness of new prescription drugs (OFFICIAL NOTICE).

As to claim 80, Kauffman does not expressly disclose a network wherein said analysis software is configured to transmit information relating to the status of a patient's disease in accordance with a universal scale. However, it would have been obvious to transmit information relating to the status of a patient's disease in accordance with a universal scale so that the patient, a doctor, or other medical professional to have access to the medical information without the need for special software (OFFICIAL NOTICE).

7. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (US Patent No.: 6,901,277) in view of Iliff (US Patent No.: 6,234,964).

As to independent claim 1, all the limitations are discussed above except: said analysis software executable on a personal computer of a patient and downloading medical images of the patient produced by the imaging apparatus to the personal computer of the patient. Kauffman does not expressly disclose said analysis software executable on a personal computer of a patient and downloading medical images of the patient produced by the imaging apparatus to the personal computer of the patient.

Iliff discloses disease management method (column 1, lines 12-14) that includes said analysis software executable on a personal computer of a patient (note that a disease management module can be executed on patient computer, see column 6, lines 59-67 and column 13, lines 12-27) and downloading medical images of the patient produced by the imaging apparatus to the personal computer of the patient (see column 8, lines 23-26, where a patient can access a database of different image modalities).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the teaching of Kaufman with the teachings of Iliff to provide a computerized disease management method for assessing the health condition of a patient having a disease e.g. chronic obstructive pulmonary disease, and optimize disease therapy based on the health assessment (column 2, lines 44-48 and column 21, lines 39-42).

As to claim independent 19, this claim differs from claim 1 only in that claim 19 is network whereas, claim 1 is method and the limitation an interface for transferring scanned images of a patient to a personal computer of the imaged patient is additively recited.

Kauffman clearly teaches a network (20, see Fig 4): an interface (30, see Fig 4) for transferring scanned images of a patient to a personal computer of the imaged patient.

As to claims 2-18, note the discussion of claim 58-75 above.

As to claim 20, Kaufman teaches network further comprising a remote database (14, see Fig 4), and wherein said analysis software is configured to instruct a personal computer to transmit information relating to status of a patient's disease to said remote database (column 13, lines 35-45).

As to claim 21, Neither Kauffman or Iliff teaches network wherein said database is maintained by a pharmaceutical company. However, it would have been obvious to have a pharmaceutical company maintain the database so that scientist at the pharmaceutical company can track the effect of medicine during a clinical trial to access the effectiveness of new prescription drugs (OFFICIAL NOTICE).

As to claim 22, Neither Kauffman or Iliff teaches a network wherein said analysis software is configured to transmit information relating to the status of a patient's disease in accordance with a universal scale. However, it would have been obvious to transmit information relating to the status of a patient's disease in accordance with a universal scale so that the patient, a doctor, or other medical professional to have access to the medical information without the need for special software (OFFICIAL NOTICE).

As to claims 23-39, note the discussion of claim 59-75 above. Claims 23-39 differ from claim 59-75 only in that claims 59-75 are method claims whereas, claims 23-39 are network claims. Thus, claims 23-39 are analyzed as previously discussed with respect to claims 59-75 above.

8. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al (US Patent No.: 6,901,277) in view of Iliff (US Patent No.: 6,234,964) further in view of in view of Chalana et al (US Patent No.: 7,158,692).

As to claim independent claim 98, all the limitations are discussed above except: a method for performing a drug treatment trial, analyzing said medical images utilizing the computer to at least one of detect, quantify, stage, report, or track a disease in the patient and uploading results of the analysis from the computer to a database for further analysis and evaluation (see column 17, lines 39-42, where the operator's findings are stored in remote database 14).

Kaufman teaches analyzing said medical images utilizing the computer to at least one of detect, quantify, stage, report, or track a disease in the patient (column 8, lines 34-36) and uploading results of the analysis from the computer to a database for further analysis and evaluation (see column 17, lines 39-42, where the operator's findings are stored in remote database 14). However, Kaufman does not disclose expressly a method for performing a drug treatment trial. Chalana discloses a medical imaging method (column 1, line 20-21) that includes performing a drug treatment trial (column 1, lines 23).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combined the teachings of Kauffman as modified by Iliff and Chalana to acquire and analyze medical images for tracking information over time, and for archiving and mining information thereby providing a seamless environment capable of enhancing clinical diagnosis and research (column 3, lines 5-14).

As to independent claim 53, note the discussion above of claim 98, all the limitations are discussed above except: said analysis software executable on personal computers of a plurality of patients and downloading the medical images of each imaged patient to the personal computer of the imaged patient. Note the discussion of claim 1 above for these limitations.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Inquires***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrae S. Allison whose telephone number is (571) 270-1052. The examiner can normally be reached on Monday-Friday, 8:00 am - 5:00 +- pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on (571) 272-7413. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information 0system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrae Allison

July 12, 2007

A.A.

SAMIR AHMED
PRIMARY EXAMINER